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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/783,897
Filing Date: February 20, 2004
Appellant(s): SANTINI ET AL.

John T. Santini Jr
Michael J. Cima
Robert S. Langer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/25/08 appealing from the Office action mailed 2/15/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Appellant states that: Claims 85 and 94 are novel over Curie (on page 11 of 35 of Appeal brief filed on 8/25/08). However, claims 85 and 94 are rejected under 35 U.S.C 103(a) as being unpatentable over Currie by Examiner. (Please see Final Office Action on page 4 mailed on 2/15/08).

Examiner made a typographic error including claims 85 and 94 under the title of rejection 35 U.S.C. 102 (b). However, under the body of rejection 35 U.S.C. 102 (b) claims 85 and 94 are not discussed. Claims 85 and 94 are rejected 35 U.S.C 103(a). There is no new ground of rejection. Please see the Final Office Action on pages 3 and 4, second paragraph mailed on 2/15/08).

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Claims 58 and 61 rejection under 35 USC § 112, first paragraph have been withdrawn in view of Appeal brief filed on 8/25/08.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

3,891,457	Auborn	6-1975
4,623,597	Sapru et al.	11-1986
5,366,454	Currie et al.	11-1994
6,537,938	Miyazaki	3-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-84, 86-93, 95-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al. (US 5,366,454).

Regarding claims 77, 89, 91 and 97-98, Currie discloses, Fig. 1-8, a medical device comprising: a substrate 12 or 22; a reservoir 16, it is noted that there is only one reservoir show in Figs. 1-6 and 8, however, there are plurality of compartment (reservoir) in the medical device (see abstract); reservoir provided in spaced positions across at least one surface of the substrate; reservoir caps (24 or 62, 64, 66, 68) covering the reservoir; and control circuitry for selectively disintegrating the reservoir caps to open the reservoirs (see abstract). Currie uses rupture method for reservoir caps to open the reservoirs for fluids

entering into the compartment/reservoir; and upon application of an electric potential generated by the control circuitry (Fig. 6).

Regarding claims 78-80, the molecules comprise molecules useful in medical diagnostics.

Regarding claims 81-83, 92-93, the substrate comprises silicon; two or more layers bonded together.

Regarding claims 84, 86-88 and 95-96, comprising a biosensor; power source. Regarding claims 85 and 94, the reservoir cap comprises a metal film (62-68). Regarding claims 89 and 102, the device adapted for implantation into a patient. Regarding claim 98, the control circuitry comprises a cathode and a power source, wherein at least one reservoir cap 24 or 24' is an anode, and wherein application of an electric potential between the cathode and anode causes at least one of the reservoir caps to disintegrate.

Regarding claims 90 and 99-101, the reservoir comprises drug molecules.

Regarding claims 102-103, it is noted that the product-by-process limitation "the reservoirs are fabricated using micro-fabrication techniques" has not been given weight in determining the patentability of the device claim. See MEPE §2113.

Claim Rejections. 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 55-76, 85 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al. (US 5,366,454).

Regarding claims 55, 60, 85 and 94, Currie discloses, Figs. 8, an implantable device comprising: a substrate 12, 22; at least two reservoirs 16 in the substrate. It shows only one reservoir, however, it is

noted that there are plurality of reservoir in the medical device (see abstract or col. 5, lines 37-40); the release system disposed in the reservoir, the release system comprising drug molecules for release; a reservoir cap 24 positioned over the reservoir; wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir, cap is actively controlled. The membrane to be ruptured and allowing body fluids to enter into the compartment (reservoir) for mixing with the medicine contained therein so that the medicine is released in admixture with the body fluids through the delivery opening into the body fluids through the delivery opening into the human body (see abstract, lines 17-27).

Currie discloses the reservoir cap (membrane 24 or 24') formed of silicon material. The silicon membrane 24' is anodically bonded to the silicon body 12 (col. 5, lines 57-58). In other words, silicon membrane can be used as anode material. Currie does not disclose the reservoir cap formed of metal. Applicant discloses his metal reservoir cap is formed of conductive material and serves as an anode (page 21, lines 24-25 or page 33, lines 30-31).

Therefore, it would have been obvious to one ordinary skill in the art substitute of one known material (such as silicon substitute for metal or vice versa), since it would have yielded predictable result (such as same anode characteristic) to one ordinary skill in the art at the time of the invention.

Additionally, Auborn (US 3,894,457) and Sapru et al. (US 4,623,597) are evidence showed that silicon (Si) and metal can be served as anode material in electrochemical.

Auborn discloses that lithium metal (col. 3, lines 25-27) or silicon (col. 3, line 46) is anode material. Sapru discloses that anode material include Zn, Nb, La, Si, Sc and Y (col. 12, line 21-22) or Cu, Mn, C, Fe, Ni, Al, Co, Mo, W, Li and Re (these are metal elements) (col. 12, lines 28-29).

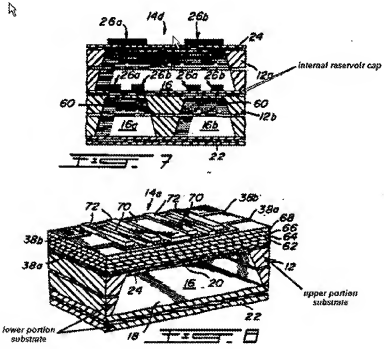
Regarding claim 56, the substrate is comprised of two or more substrate (12 and 22) portion bonded together.

Regarding claim 57, the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap (see Fig. 8 below).

Regarding claim 58, as best as understood, wherein a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion and the two reservoir sections forming a single reservoir (see Fig. 8 below).

Regarding claim 59, the reservoir section in the lower substrate has a volume that is greater than the volume of the reservoir section in the upper substrate portion.

Regarding claims 61-62, (Fig. 7 below), the substrate comprises an upper substrate portion 12a adjacent the reservoir cap and a lower substrate portion 12b distal the reservoir cap; wherein the lower substrate portion is provided with an internal reservoir cap interposed between a reservoir section of the upper substrate portion and a reservoir section of the lower substrate portion, wherein release of the molecules from the reservoir section in the lower substrate portion is controlled by diffusion through or disintegration of the internal reservoir cap.



Regarding claims 63-64, the disintegration of the reservoir cap is activated by application of electrical energy through the reservoir cap (see abstract, and Fig. 6).

Regarding claims 65-67, Currie discloses the claimed invention except for the release system comprises matrix material or biodegradable or bioerodible polymeric material; and the drug molecules comprises anesthetics, vaccines, chemotherapeutic, etc ....It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials mentioned above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 68, the disintegration of the reservoir caps is controlled by a preprogrammed microprocessor.

Regarding claims 69-76, similar to rejection of claims 55-68 above. Furthermore, Currie discloses that the device is activated by disintegration of the reservoir cap by direct application of an electrical potential through the reservoir cap (see abstract; or col. 2, lines 47-65).

(10) Response to Argument

I. Claims 77-84, 86-93, 95-103 are rejected under 35 U.S.C 102(b) as being anticipated by Currie et al. (US 5,366,454).

Appellant argues that:

1. The reservoir caps are selectively disintegrable. Disintegrating Appellants' reservoir caps is not the same as rupturing Currie's fragile membrane. Currie fails to disclose Appellants' claimed feature of disintegrating the reservoir caps, and that the claims are not anticipated.

In response, Appellant acknowledges in the Appeal Brief on page 11 of 35 that : the reservoir caps are formed of materials that passively disintegrate, materials that allow the molecules to diffuse passively out of the reservoir over time, or materials that disintegrate upon application of an electric potential. (Also see page 4, lines 3-6 of Specification).

Similarly, Currie discloses that when the reservoir cap/ membrane 24 ruptures or disintegrates, the body fluids in the device 10 enter into the compartment 16 in response to an electric signal (col. 5, lines 59-68, col. 6, lines 29-34, lines 60-65).

Additionally, the definition of disintegration includes the condition of being decayed; breakdown, decomposition (see www.answers.com). Similarly, "rupture" means that the process or instance of breaking open or bursting, or the state of being broken open.

Therefore, the drug molecule it is clear that the "rupturing" of Currie's cap 24 equates to the "disintegrating" as claimed by applicant.

II. Claims 97-98 are rejected under 35 U.S.C 102(b) as being anticipated by Currie et al. (US 5,366,454).

Appellant argues that nothing in Currie mentions: the reservoir cap disintegration comprises "dissolving into solution, or forming soluble ions or oxidation compounds, upon application of an electric potential generated by the control circuitry.

In response, Currie clearly discloses that the reservoir cap/membrane 24 has ruptured in response to an electric signal (col. 5, lines 59-62). Once the reservoir cap/membrane 24 has ruptured, body fluids of the animal or human in which the device 10 is implanted enter into the compartment 16 and mix (dissolving into solution) with the medicine contained therein so that the medicine is released in admixture (dissolving into solution) with the body fluids through the delivery opening 20 into the animal or human (col. 6, lines 60-65). Furthermore, Currie discloses that the reservoir cap/membrane cap 60 are mixing (dissolving into solution) of the medicine contained in reservoir/compartment 16 and 16b (col. 8, lines 1-10).

III. Claims 85 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al. (US 5,366,454).

1. Appellant states that "Currie neither expressly nor inherently discloses reservoir caps comprising a metal film, the reference does not anticipated Appellant's claim 85 and 94.

As mentioned earlier, under Section (6) **Grounds of Rejection to be Reviewed on Appeal,**

Examiner made a typographic error including claims 85 and 94 under the title of rejection 35 U.S.C. 102 (b). However, under the body of rejection 35 U.S.C. 102 (b) claims 85 and 94 are not

discussed. Claims 85 and 94 are rejected 35 U.S.C 103(a). There is no new ground of rejection. Please see the Final Office Action on pages 3 and 4, second paragraph mailed on 2/15/08).

2. Appellant argues that Currie does not disclose the reservoir cap formed of metal. Currie fails to disclose that the rupturable membrane necessarily is a metal film and the Examiner has provided no evidence or reasoning to support even an inference that the rupturable membrane necessarily is a metal film.

In response, Examiner admits that Currie discloses the reservoir cap (membrane 24 or 24') is formed of silicon material. The silicon membrane 24 is anodically bonded to the silicon body 12 (col. 5, lines 37-58). In other words, the silicon membrane can be used as an anode material. Currie does not disclose the reservoir cap formed of metal. Appellant acknowledges that his metal reservoir cap is formed of conductive material and serves as an anode (page 21, lines 24-25 or page 33, lines 30-31). Therefore, it would have been obvious to one of ordinary skill in the art to substitute such known conductive materials for each other (such as silicon substitute for metal or vice versa), since it would have yielded similar results (such as same anode characteristics) to one ordinary skill in the art at the time of the invention.

3. As Appellant has requested, the Examiner must provide evidence that supports the assertion that the rupturable membrane/reservoir cap made of silicon serve as anode can be substitute for other material such as metal serves as anode.

In response,

According to MPEP, Chapter 2100, under 2144.03 section:

2144.03 [R-6] Reliance on Common Knowledge in the Art or "Well Known" Prior Art

In *>certain< circumstances >where appropriate<, ** an examiner *>may< take official notice of facts not in the record or * rely on "common knowledge" in making a rejection, however such rejections should be judiciously applied.

PROCEDURE FOR RELYING ON COMMON KNOWLEDGE OR TAKING OFFICIAL NOTICE

The standard of review applied to findings of fact is the "substantial evidence" standard under the Administrative Procedure Act (APA). See *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 1216.01. In light of recent Federal Circuit decisions as discussed below and the substantial evidence standard of review now applied to USPTO Board decisions, the following guidance is provided in order to assist the examiners in determining when it is appropriate to take official notice of facts without supporting documentary evidence or to rely on common knowledge in the art in making a rejection, and if such official notice is taken, what evidence is necessary to support the examiner's conclusion of common knowledge in the art.

Therefore, Examiner would like to prove these two evidence references Auborn (US 3,894,457) and Sapru (US 4,623,597) to support the evidence that the rupturable membrane/reservoir cap made of silicon serve as anode material can be substitute for metal material. There is no new of ground rejection. Examiner also provides these evidences on previous Final Office Action mailed on 2/15/08. Please see on pages 5 and 8 of Previous Final Office Action.

Auborn (US 3,894,457) and Sapru et al. (US 4,623,597) are evidence showed that silicon (Si) and metal can be served as anode material in electrochemical.

Auborn discloses that the anode is an oxidizable material and is preferably lithium metal (col. 3, lines 25-27). Other ozidizable anode materials include the alkaline earth metal (col. 3, lines 27+) or silicon (col. 3, line 46) is anode material. Therefore, it would have been obvious to one ordinary skill in the art substitute of one known material such as silicon substitute for metal to serve as anode, since it would have yielded predictable result to one ordinary skill in the art at the time of the invention.

Sapru discloses that other materials tested also showed suitability for use as an anode material include Zn, Nb, La, **Si (silicon)**, Sc and Y (col. 12, line 21-22) or Cu, Mn, C, Fe, Ni, Al, Co, Mo, W, Li and Re (these are metal elements) (col. 12, lines 28-29). Therefore, it would have been obvious to one ordinary skill in the art substitute of one known material such as silicon substitute for metal to serve as anode, since it would have yielded predictable result to one ordinary skill in the art at the time of the invention.

IV. Claims 55-76, 85 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Currie et al. (US 5,366,454).

1. Appellant argues that Currie fails to teach or suggest disintegratable reservoir caps.

In response, as disused above in Part I, Appellant acknowledge in Appeal Brief on page 11 of 35 that : the reservoir caps are formed of materials that passively disintegrate, materials that allow the molecules to diffuse passively out of the reservoir over time, or materials that disintegrate upon application of an electric potential. (Also see page 4, lines 3-6 of Specification).

Similarly, Currie discloses that a reservoir cap/ membrane 24 has ruptured or disintegrate, the body fluids in the device 10 is implanted enter into the compartment 16 in response to an electric signal (col. 5, lines 59-68, col. 6, lines 29-34, lines 60-65)

Additionally, the definition of disintegration means that the condition of being decayed; breakdown, decomposition (see www.answers.com). Similarly, rupture means that the process or instance of breaking open or bursting, or the state of being broken open.

Therefore, the drug molecule is released from the device of Currie by disintegration/ruptures of the reservoir cap 24 or 24'.

2. Appellant argues that Currie fails to teach or suggest metal or electrically conductive /metal reservoir cap. Currie discloses only silicon membranes and does not disclose or suggest metal or electrically conductive reservoir caps

In response, Appellant discloses conductive material (such as metal) reservoir cap serves as anode material (page 21, lines 24-25 or page 33 and lines 30-31) to process of disintegration (or breakdown) the cap.

Meanwhile, Currie does not disclose the reservoir cap made of electrical conductive material such as metal. However, Curie clearly discloses that the reservoir cap or silicon membrane 24 has ruptured (or disintegration or breakdown). Curie further discloses that a silicon membrane 24 or 24' is **anodically bonded** to the silicon body 12, 12' (col. 5, lines 57-58).

As noted that, "anodically bonded" or "anodic bonding" is a method using the **silicon as anode** and the glass as a cathode by heated to certain temperature (col. 1, lines 28-31).

Therefore, it would have been obvious to one ordinary skill in the art substitute of one known material (such as silicon substitute for metal or vice versa), since it would have yielded predictable result (such as same anode characteristic) to one ordinary skill in the art at the time of the invention.

Furthermore, Examiner would like to use additional reference such that Miyazaki (US 6,537,938) is evidence to prove that silicon can be served as anode in "anodically bonded or anodic bonding" method. Miyazaki (US 6,537,938) discloses that anodic bonding is a method wherein a glass is heated to a temperature at which readily mobile cation contained in the glass are readily mobile, and using the **silicon as an anode** and the glass as a cathode (col. 1, lines 28-33).

Based on what Miyazaki explains about anodic bonding method, one skill in the art would recognize that Currie uses silicon membrane 24 as an anode.

Furthermore, Applicant also acknowledges that similar to what Examiner explained above that the electrons from the Si are drawn to the anode (Remarks filed on 12/12/07 on page 16, line 9) as below:

> Secondly, Examiner makes an incorrect analogy. Currie does disclose that the silicon reservoir membrane 24 is anodically bonded to the silicon body 12, but it appears that Examiner does not understand what that term of art means. It is understood in the art of microfabrication that silicon is anodically bonded to silicon by using Pyrex glass, e.g. sodium rich Pyrex Corning #7740, as an intermediary, either in the form of a Pyrex thin film or Pyrex deposited (e.g. sputtered) on the surface of a silicon wafer. A large voltage (e.g. 1000 V) is then applied, with the negative cathode coupled to the Pyrex glass and the positive anode coupled to the silicon wafer. The voltage creates migration of Na^+ ions in the glass towards the cathode which leaves a negative charge at the interface which, as the electrons from the Si are drawn to the anode, attracts the Si^{++} ions from the silicon wafer to form a strong SiO_2 interface to bond the silicon wafer to the glass. This allows the formation of SiO_2 at a thin interface layer to bond one silicon wafer to another silicon wafer by bonding each silicon wafer to opposite sides of the Pyrex interlayer. This is discussed in the standard treatise Fundamentals of Microfabrication: The Science of Miniaturization, Madou, M., 2d ed. At pp. 484-485 (CRC Press 2002). Thus, in the

Conclusion, one skill in the art would recognize that instead of using silicon reservoir cap 24 as anode. It can be substitute metal material of reservoir cap and serve anode as well.

3. Appellant argues that Currie does not require the passage of electricity through the reservoir cap.

In response, the device of Currie must be needed the passage of electricity through to breakdown or rupture the reservoir cap/membrane 24 (col. 5, lines 60-62).

4. Appellant argues that Examiner reasons that since silicon and metal allegedly can serve as anode material in electrochemical cells, as evidenced by Auborn (US 4,623,597) or Sapru et al. (US 4,623,597), it would be obvious to substitute metal for the silicon membrane in Curie. The Examiner's hindsight-driven conjecture lacks a sound legal or factual basis.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and

does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

5. Appellant argues that Examiner incorrectly cites Miyazaki as evidence that in anodic bonding silicon is used as an anode.

As discussed above, Miyazaki (US 6,537,938) clearly discloses that anodic bonding is a method wherein a glass is heated to a temperature at which readily mobile cation contained in the glass are readily mobile, and using the **silicon as an anode** and the glass as a cathode (col. 1, lines 28-33).

Based on what Miyazaki explains about anodic bonding method, one skill in the art would recognize that Currie uses silicon membrane 24 as an anode.

Furthermore, Applicant also acknowledges that similar to what Examiner explained above that the electrons from the Si are drawn to the anode (Remarks filed on 12/12/07 on page 16, line 9) as below:

> Secondly, Examiner makes an incorrect analogy. Currie does disclose that the silicon reservoir membrane 24 is anodically bonded to the silicon body 12, but it appears that Examiner does not understand what that term of art means. It is understood in the art of microfabrication that silicon is anodically bonded to silicon by using Pyrex glass, e.g. sodium rich Pyrex Corning #7740, as an intermediary, either in the form of a Pyrex thin film or Pyrex deposited (e.g. sputtered) on the surface of a silicon wafer. A large voltage (e.g. 1000 V) is then applied, with the negative cathode coupled to the Pyrex glass and the positive anode coupled to the silicon wafer. The voltage creates migration of Na^+ ions in the glass towards the cathode which leaves a negative charge at the interface which, as the electrons from the Si are drawn to the anode, attracts the Si^+ ions from the silicon wafer to form a strong SiO_2 interface to bond the silicon wafer to the glass. This allows the formation of SiO_2 at a thin interface layer to bond one silicon wafer to another silicon wafer by bonding each silicon wafer to opposite sides of the Pyrex interlayer. This is discussed in the standard treatise Fundamentals of Microfabrication: The Science of Miniaturization, Madou, M., 2d ed. At pp. 484-485 (CRC Press 2002). Thus, in the

Therefore, one skill in the art would recognize that silicon can be served as an anode in an anodic bonding method.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Quynh-Nhu H. Vu/

Examiner, Art Unit 3763

Conferees:

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